HEARING TESTIMONY

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Good morning Chairman Tester, Ranking Member Vitter, Members of the Committee, ladies, and gentlemen. My name is Robert Bargatze, and I am Executive Vice President and Chief Scientific Officer of Ligocyte Pharmaceuticals, Inc. I want to thank you for the opportunity to speak with you today about the unique hurdles to accessing capital that innovative biotech startups face. Make no mistake, biotechnology has incredible potential to unlock the secrets to curing devastating disease and helping people to live longer, healthier, and more productive lives, but the barriers that small biotech companies encounter on a daily basis raise some important questions: Would we rather see the next generation of breakthrough cures discovered by researchers in Bozeman or Beijing? Do we want the jobs associated with this groundbreaking science to go to workers in Missoula or Malaysia? If we want more scientific breakthroughs that allow us to enjoy a high quality of life – indeed, breakthroughs that save the lives of our loved ones – then shouldn't we put in place policies that encourage innovation through private investment?

While the biotechnology industry faces significant challenges, we nonetheless have the ability to deliver the next generation of cures and treatments to the bedsides of patients who desperately need them while at the same time creating a healthier American economy. The 1.42 million Americans directly employed by biotech are driven to treat and heal the world, but in order for them to be able to do that, Congress must remove the barriers to innovation that we face. Innovation in biotechnology leads to the medical breakthroughs that cure and treat devastating diseases like cancer and Alzheimer's and allow real people to see their grandkids graduate from college or walk their daughters down the aisle.

The leash that holds our industry back from helping more people is, in large part, the devastating effect that a lack of access to necessary capital can have on growing biotech companies. Today, Congress has the opportunity to help speed lifesaving cures and treatments to patients by bolstering capital formation in our industry.

My company, Ligocyte, is a private biopharmaceutical company based in Bozeman, Montana that is developing innovative vaccine products based on our virus-like particle (VLP) platform.

VLP technology provides anti-viral protection without the complexity associated with live viruses. Our lead product candidate, a VLP-based vaccine designed to prevent gastroenteritis caused by norovirus, just completed a Phase I/II study which showed proof-of-principle in humans. I co-founded Ligocyte in 1998, and we currently have 38 employees.

I am also the Chairman of the Montana BioScience Alliance, which fosters partnerships among the various biotech stakeholders in Montana in order to grow and sustain a globally competitive bioscience industry in our state. Our relationships with entrepreneurs, laboratories, hospitals, clinics, and universities allow Montana biotechnology companies to create high-quality jobs and economic opportunity for the people of Montana.

When I co-founded Ligocyte in 1998, we were the quintessential small business. My four co-founders and I each gave the new company $5,000 to get things off the ground – our very first round of financing. With our startup funds, we bought kitchen cabinets from the home improvement store down the street and installed them ourselves, giving us our first laboratory shelves in our new workspace. Our location in the Advanced Technology Park near Montana State University put us in prime position to succeed, but we had no cash on hand past our initial personal investment. Our first contracts were for high content screening with large pharmaceutical companies like Merck and SmithKline to facilitate selection of lead product candidate anti-inflammatory drugs. These small revenue streams generated income to cover our overhead while we wrote our Small Business Innovation Research (SBIR) grant proposals.

SBIR gave us the jumpstart we needed to move forward with our own projects. SBIR is targeted specifically at small, innovative companies like ours, and it was a key foundation of Ligocyte's success in Montana. Because of our SBIR grants, we could focus on our vaccines and make important progress in our research. We were able to leverage this progress into a contract to do biodefense vaccine development work for the Department of Defense (DoD). With our success on our DoD contract, we were finally able to get our first round of venture financing. Venture capital is the lifeblood of the biotechnology industry around the country, and our early partnerships with two small venture firms in the Rockies allowed us to fund Phase I clinical trials in our vaccine pipeline. The data from those trials was instrumental in getting buy-in from larger investors, which has pushed our research to where it is today. Four years ago, we attended the Montana Economic Development Summit, hosted by Montana Senator Max Baucus. We successfully presented our Phase I data there to Forward Ventures and subsequently met with several interested venture capital funds, including Fidelity BioVentures and those affiliated with the large biopharmaceutical companies MedImmune and Novartis. These relationships led to a $28 million round of venture financing.

We are currently entirely privately funded, with the exception of our ongoing contracts with the Department of Defense. As you can see, getting to this point was no easy task. Even as the Chief Scientific Officer, I always had to keep one eye open for financing opportunities to further our research. There is no "beaten path" for small companies like ours to follow. Instead, we have to break new ground, both in our science and in our search for funding. It is not a simple undertaking, and many companies are not as successful as Ligocyte has been. Their science might be just as groundbreaking as ours, but if the funding cards do not fall the right way the science hardly matters.

As Chairman of the Montana BioScience Alliance, I have heard numerous stories of other biotech startups going through the same process that Ligocyte did. The first years of a private biotech consist of cobbling together funding from any source possible until a larger revenue stream opens up. Ligocyte was lucky enough to be researching vaccines, as our biodefense contract with the Department of Defense was an important financing milestone in our early development as a company. However, most startups do not have a pipeline that lends itself quite so easily to large biodefense contracts. Companies researching treatments for cardiovascular disease, the leading cause of death in the United States; diabetes, one of the fastest-growing ailments in the population; or cancer, the largest biotechnology research space, would get no interest from DoD, leaving them in an even weaker position when seeking venture capital financing.

There are thousands of companies facing similar funding struggles throughout the United States, each one with molecules and product candidates that could change the face of modern medicine. Biotechnology may hold the answers to the medical problems that America faces, from the devastation of cancer and HIV/AIDS to the personal losses of Alzheimer's and Parkinson's to the spiraling costs of health care associated with diseases of epic proportions, such as Type 2 diabetes. Of the 118 scientifically novel drugs approved from 1998 to 2007, 48% were discovered and/or developed by biotech companies. These revolutionary cures and treatments save lives, provide a higher quality of life, and reduce long-term healthcare costs. As Congress continues to look for ways to reduce our nation's deficit, it is important that we remember the impact that innovative medicines can have on increasing overall health, especially by combating costly chronic diseases. These advances will save taxpayers money by decreasing the outlays necessary to care for our aging population.

Additionally, the biotech industry is a thriving economic growth engine, directly employing 1.42 million Americans in high-quality jobs and indirectly supporting an additional 6.6 million workers. The average biotechnology employee makes $77,595 annually, far above the national average salary. President Obama has called for the United States to lead in the 21st century innovation economy, and biotechnology can be a key facet of our nation's economic growth. Montana is among the leaders of this growth – the bioscience sector in our state spends more on R&D per capita than the bioscience sectors in all but 13 states.

Despite these windows of opportunity, biotechnology research and development is often a difficult process. Bringing groundbreaking cures and treatments from bench to bedside is a long and arduous road, and small biotechnology companies are at the forefront of the effort. It takes an estimated 8 to 12 years for one of these breakthrough companies to bring a new medicine from discovery through Phase I, Phase II, and Phase III clinical trials and on to FDA approval of a product. The entire endeavor costs between $800 million and $1.2 billion. Due to this capital-intensive process, biotechnology companies lacking research and development funds turn to private sector investors and collaborative agreements to finance the early stages of development.

However, the current economic climate has made private investment dollars extremely elusive. In 2010, venture capital fundraising endured its fourth straight year of decline and its worst since 2003. Biotechnology received just $2 billion in venture funding, a 27 percent drop from its share

in 2009. Even worse, the biggest fall was seen in initial venture rounds, which are the most critical for early-stage companies. Series A deals last year brought in just over half of what they did in 2009. Decreasing upfront investment could mean cures and treatments being shelved in labs across the nation and ultimately not reaching patients. Generally, venture capitalists are challenged by significantly reduced capital flowing into their funds on the front end and are having to hold their investments longer before exiting due to the weakness of the public markets. This has led to venture funds deploying capital differently than in the past, to biotech's disadvantage.

Montana startups are at a particular disadvantage due to the dearth of venture capital firms in and around our state. Although the Montana BioScience Alliance has taken steps to increase university partnerships, find firms that specialize in biotech construction and intellectual property protection, and propel scientific and management expertise to Montana companies, it remains the case that funding sources are few and far between among the Rocky Mountains. In fact, Senator Baucus's Economic Development Summit is one of the only efficient ways for startup biotechnology companies in our state to connect with venture capitalists. Small biotech companies in Montana are almost all private and are largely reliant on SBIR and other government programs like the Therapeutic Discovery Project (TDP). However, government funding combined with investment from a company's founders is not enough to pilot a clinical study or investigate potential new treatments. The high cost and long development period associated with bringing a new medicine to market make private capital necessary, often in the form of angel investors and venture capitalists. Ligocyte has been fortunate thus far, but the high-risk nature of biotech development and the gloomy economic climate have made investors reluctant.

The shift in the economy has also harmed companies like mine that already have venture financing. Historically, venture capitalists receive a return on their investment when a company goes public through an initial public offering (IPO). The cash raised through the IPO would provide an exit for these early investors as well as provide the capital to fund expensive Phase II and Phase III trials at the company. However, the IPO market is essentially closed at the moment. From 2004 to 2007, the United States had an average of 34 IPOs in biotechnology per year. In 2010, there were only 17. Although the funding level of biotech IPOs is increasing from its recession-induced nadir, this progress has been made almost entirely by larger, more mature companies. The two largest transactions in the industry last year were completed by a company in Phase III trials and a next-generation sequencing company that was already generating revenue. The weak demand for these public offerings for smaller companies is restricting access to capital. This then hampers critical research, forces companies to stay private for longer, and depresses valuations of later-stage venture rounds.

As U.S. biotech companies face financial uncertainty, other countries are increasing their investments and enacting intellectual property protections to encourage their own biotech growth. The United States still holds its place as the leader in global biotechnology patents thanks to our large head start, but China and India rank first and second in biotech patent growth. These emerging powers are heavily investing in science, and particularly in biotechnology. Meanwhile, the U.S. has fallen to 20th out of 23 countries in new biotech patent applications. A recent survey conducted by BIO found that nearly a third of small biotech companies have been

approached to move their R&D operations offshore, and CEOs named China and India as two prime destinations. Furthermore, since 2008, trouble in the IPO market has decreased the number of public biotech companies in the U.S. from 394 to just 302, a 23% drop. Meanwhile, China's biotech IPO market continues to grow – in 2010, 33 bioscience IPOs in China raised $5.9 billion, an increase of 47% over 2009. The venture capital and private equity market is thriving in China as well, increasing funding levels by over 200% in the past two years. Meanwhile, companies here in the United States struggle to find funding from any number of sources, not all of which prove fruitful. In Montana, we have found that novel financing sources are few and far between, and innovation capital is dwindling. It is imperative that financing is robust and available to encourage continued biotech innovation in the U.S., enhance American competitiveness on the global stage, and ensure that the United States maintains a healthy and growing innovation economy.

Modifications to Current Federal Programs Impacting Innovative Biotech Companies

Congress and the Administration have taken some notable steps to help companies facing these financial struggles. By providing funding to innovative companies and incentivizing investment in small businesses, certain programs have proven invaluable to companies like mine. However, Congress can increase the impact of these important programs by making modifications to ensure that they have the largest possible effect on innovation.

Small Business Innovation Research (SBIR) Program

As I have already mentioned, SBIR was a potent lifeline for Ligocyte during our early stages of development. The SBIR program is structured so that 2.5 percent of all federal R&D grant monies are reserved for small business applicants. These funds provide critical seed money to new business innovators like the biotech startups in Montana. However, the eligibility rules for small businesses to qualify for SBIR have excluded biotech companies since 2003. In particular, the size standard limits eligibility to companies that are majority owned and controlled by individuals who are U.S. citizens (or resident aliens). While the congressional intent of this definition was to keep funding in the United States, the Small Business Administration (SBA) has interpreted it differently. In 2001, after Ligocyte had already received our SBIR grants, the SBA Office of Hearings and Appeals ruled that the definition of "individuals" only applied to "natural persons," and not to entities such as venture capitals funds, pension funds, or corporations. In 2003, SBA specifically applied this ruling to biotechnology companies funded by venture capitalists. This effectively barred venture-backed companies from receiving SBIR funds, a drastic change from the program's implementation since 1982.

In order for biotechnology companies to be successful, they must tap into venture capital funding. Ligocyte, for instance, meets virtually every definition of the "small, high-tech, innovative" businesses that SBIR purports to help; however, we are not currently eligible for SBIR grants because we are majority owned by venture capital companies. Other companies like Ligocyte that are not as far along the development pathway have been similarly barred from the program. I have seen the impact the SBIR program has had on the biotechnology industry, not only by fostering the growth of fledgling companies during some of the most challenging times in their business cycles, but also by enhancing the advancement of important cures and

treatments to the marketplace. However, the current rules have inhibited the growth and survival of small private biotechnology companies due to the inability of venture-backed companies to participate in the SBIR program. I believe that Congress should restore SBIR eligibility to majority venture-backed companies in order to truly incentivize breakthrough innovation.

Therapeutic Discovery Project (TDP)

Another program which has helped Ligocyte and other small biotechnology companies is the Therapeutic Discovery Project (TDP). Last March, Congress enacted this important tax credit program designed to stimulate investment in biotechnology research and development. Under this program, small biotech companies received a much-needed infusion of capital to advance their innovative therapeutic projects while creating and sustaining high-paying, high-quality American jobs.

In total, the Therapeutic Discovery Project awarded $1 billion in grants and tax credits to nearly 3,000 companies with fewer than 250 employees each. These small companies were eligible to be reimbursed for up to 50% of their qualified investment in activities like hiring researchers and conducting clinical trials. The impact of this funding was felt across the American biotech industry, as companies in 47 states received awards. The average company received just over $200,000, an important shot in the arm in these rough economic times.

Ligocyte received two awards under TDP, both for the maximum amount of $244,479. Our nearly $500,000 TDP allotment has been a valuable resource to our company. As a result of this funding, we were able to hire one new researcher and keep the rest of our 44 workers employed at salaries that reflects the hard work they put in. The cash influx that TDP provided also helped us advance our research. One of our grants was for our VLP-based norovirus vaccine which, as I have mentioned, recently showed proof-of-principle in a Phase I/II trial. Additionally, we received a grant for another candidate in our pipeline, a VLP-based vaccine to prevent respiratory disease.

The infusion of capital for small biotech companies provided by the Therapeutic Discovery Project is an essential incentive for companies to keep their research and development, manufacturing, and operations here in the United States. The critical funding will also accelerate the movement of cures and treatments to patients who need them. This program was a step in the right direction by Congress to invest in growing the U.S. biotech industry to keep pace with our global competitors. Given the imbalance between the extraordinarily high demand by small biotech companies and the limited pool of funds, I hope that Congress will extend and expand this oversubscribed program and assist more American companies in pursuing life-saving scientific breakthroughs and supporting American jobs.

Financial Services Capital Formation Proposals

The breadth of the financing problem in the biotechnology industry calls for comprehensive solutions to ease capital formation, involving both tax and financial services policy. In addition to the difficult financing landscape and struggling public markets, growing biotech companies also face regulatory burdens which further hinder capital formation in our industry. Making

changes to regulations which unintentionally harm the biotech industry would free companies to focus their efforts on their innovative scientific research rather than complex reporting and compliance. I believe that changes to Sarbanes-Oxley Section 404(b), SEC Rule 12b-2, SEC Regulation A, and the SEC reporting standard could provide great benefit to groundbreaking biotechnology companies.

Sarbanes-Oxley Section 404(b) (Financial Reporting)

The Sarbanes-Oxley Act (SOX) was enacted to protect investors by bringing greater transparency to public companies. While the financial reporting requirements in SOX continue to provide this important service, Section 404(b) imposes a disproportionately negative cost burden on smaller public companies.

The biotechnology sector is especially disadvantaged by the compliance burden of Section 404(b) due to the unique nature of our industry. The long, capital-intensive development period intrinsic to biotechnology often causes companies to have a relatively high market capitalization (caused by multiple rounds of venture financing prior to going public) but little-to-no revenue. Therefore, many biotech companies facing their first few years on the public market are forced to divert funds from scientific research and development to Section 404(b) compliance. The opportunity cost of this compliance can prove damaging, resulting in already limited resources being driven away from a company's search for cures and treatments.

Further, the true value of biotech companies is found in non-financial disclosures such as clinical trial milestone results, FDA approvals, and patent status. Investors often make decisions based on these development milestones rather than the financial statements mandated by Section 404(b). Thus, the financial statements required do not provide much insight for potential investors, meaning that the high costs of compliance far outweigh its benefits.

Section 989G of the Dodd-Frank Wall Street Reform and Consumer Protection Act is an important acknowledgment by Congress that Section 404(b) of Sarbanes-Oxley is not an appropriate requirement for many small reporting companies. Dodd-Frank sets a permanent exemption from Section 404(b) for companies with a public float below $75 million; however, this is too narrow in practicality and must be raised. In 2006, the SEC Small Business Advisory Board recommended that the permanent exemption be extended to companies with public floats less than $700 million. The Advisory Board's proposed ceiling would allow small innovative companies to focus on speeding cures and treatments to patients rather than SOX compliance.

The Advisory Board also realized that public float alone does not fully portray the complexity and risk associated with a reporting company, and suggested a revenue test to paint a fuller picture. Revenue should be a critical consideration when determining the appropriateness of Section 404(b) compliance, along with public float. The addition of a revenue test would better serve the congressional intent behind Sarbanes-Oxley by reflecting the truly small nature of companies with little or no product revenue. Public companies with a public float below $700 million and with product revenue below $100 million should be permanently exempt from Section 404(b), allowing them to focus on their critical research and development.

SEC Rule 12b-2 (Filing Status Definitions)

Amending the filing status definitions found in SEC Rule 12b-2 would be another way to reduce the 404(b) compliance burden on small innovative companies.

SEC Rule 12b-2 establishes three distinct classifications by which companies determine their filing status: large accelerated filers – companies with a public float of more than $700 million; accelerated filers – those with a public float of more than $75 million but less than $700 million; and non-accelerated filers – companies with a public float of less than $75 million (known as smaller reporting companies).

Because a particular filing status carries with it onerous regulatory duties and compliance costs (such as compliance with SOX Section 404(b)), finding a method of designation that fairly captures a company's profile is essential. While using public float as a primary metric for determining filing status is a good first step, it fails to take into account other relevant factors that more accurately measure the size and complexity of certain industries or categories of companies. The biotechnology industry provides a telling example.

Biotech companies often have a relatively large public float because of the potential of the groundbreaking cures and treatments they are developing. However, as I have discussed, the extended R&D timeline that we face calls for a long-term commitment and considerable private funding. During the long development period, small biotech companies commonly have no revenue or operate at a loss. If revenue was taken into account in determining filing status, then companies with little to no revenue but a high public float could avoid the financial burdens of certain auditing requirements with which larger, more established companies must comply. Revising the definition of smaller reporting companies to include a revenue component would reflect the true nature of startup biotechnology companies and allow them to focus on their groundbreaking science.

Additionally, the current quantitative metrics for determining filer status under Rule 12b-2 also need revision. The definitions of filer status were created to offer unique classifications based on filer characteristics and determine the breadth of regulatory compliance to which filers must adhere. As I have mentioned, the markers are currently set at $75 million and $700 million, dividing filers into three groups. When these definitions were set, they provided an accurate depiction of the groups above and below the markers. Since then, however, the market has continued to evolve and these markers have become outdated. In particular, the $75 million public float cap for smaller reporting companies does not match current market conditions. I believe that a $250 million cap for non-accelerated filers would group companies with common characteristics together, as the rule originally intended to do, rather than split them at the outdated $75 million point.

SEC Regulation A (Direct Public Offerings)

Regulation A, adopted by the SEC pursuant to Section 3(b) of the Securities Act of 1933, was created to provide smaller companies with a mechanism for capital formation with streamlined

offering and disclosure requirements. Updating it to match today's market conditions could provide an important funding source for small biotechnology companies.

Regulation A allows companies to conduct a direct public offering valued at less than $5 million while not burdening them with the disclosure requirements traditionally associated with public offerings. The idea behind Regulation A was to give companies which would benefit from a $5 million influx (*i.e.*, small companies in need of capital formation) an opportunity to access the public markets without weighing them down through onerous reporting requirements.

However, the $5 million offering amount has not been adjusted to fit the realities of the current market and Regulation A is not used by small companies today. The current threshold was set in 1980 and is not indexed to inflation, pushing Regulation A into virtual obsolescence. As it stands, a direct public offering of just $5 million does not allow for a large enough capital influx for companies to justify the time and expense necessary to satisfy even the relaxed offering and disclosure requirements.

I believe that Regulation A could have a positive impact for small biotechnology companies if its eligibility threshold was increased from $5 million to $50 million while maintaining the same disclosure requirements. This increase would allow companies to raise more capital from their direct public offering while still restricting the relaxed disclosure requirements to small, emerging companies. Regulation A reform could provide a valuable funding alternative for small biotech startups, giving them access to the public markets at an earlier stage in their growth cycle and allowing them to raise valuable innovation capital.

SEC Reporting Standard (Shareholder Limit)

Although SEC policies like Rule 12b-2 and Regulation A are designed to monitor public companies, the agency also keeps tabs on private companies when they reach a certain size. Modifying the SEC's public reporting standard would prevent small private biotechnology companies from getting unnecessarily burdened by shareholder regulations.

Once a private company has 500 shareholders, it must begin to disclose its financial statements publicly. Biotechnology companies are particularly affected by this 500 shareholder rule due to our industry's growth cycle trends and compensation practices. As I have mentioned, the IPO market is essentially closed to biotechnology, leading many companies to choose to remain private for at least 10 years before going onto the public market. This long timeframe can easily result in a company having more than 500 current and former employees, most of whom have received stock options as part of their compensation package. Under the SEC's shareholder limit, a company with over 500 former employees holding stock, even if it had relatively few current employees, would trigger the public reporting requirements. Exempting employees from any shareholder limit is a minimum necessary measure to ensure growth-stage biotech companies are able to hire the best available employees and compensate them with equity interests, allowing them to realize the financial upside of a company's success.

Also, including accredited investors in the private company shareholder count does not serve the intended purpose of protecting retail investors. The SEC recognizes that accredited investors are

a unique class that does not require the same level of protection as other investors. By including them in the 500 shareholder limit, growth-stage private companies are forced to rely primarily on institutional investors because they need to maximize funding without triggering the limit. This excludes retail investors, who the SEC was originally trying to protect, from taking part in this process.

Additionally, increasing the shareholder limit from 500 to 1000 would relieve small biotech companies from unnecessary costs and burdens as they continue to grow. As it stands, the limit encumbers capital formation by forcing companies to focus their investor base on large institutional investors at the expense of smaller ones that have been the backbone of our industry. Further, it hinders a company's ability to compensate its employees with equity interests and negatively affects the liquidity of its shares. Increasing the shareholder limit and exempting employees and accredited investors from the count are measures that, together, would remove significant financing burdens from small, growing companies.

New Tax Proposals Encouraging Private Biotech Company Investment

While modifications to onerous regulations would provide key improvements to the biotechnology investment environment, Congress has the opportunity to enact new incentives that could open new sources of capital for small biotechs. Though this committee does not have jurisdiction over tax issues, I would like to take this opportunity to highlight a few tax policies that could be valuable in incentivizing private investment. There are a number of new proposals, including the modifications to IRC Section 1202, the House-passed Small Business Early-Stage Investment Program, an angel investor tax credit, and partnership structures to support high-risk innovative industries, which could incentivize biotechnology investment.

Reduced Capital Gains Rate for Sale of Qualified Small Business Stock (IRC Section 1202)

Congress has striven to aid startup companies by providing investors in qualified small businesses preferential capital gains tax treatment on the return on their investments. Section 1202 of the Internal Revenue Code covers this reduced capital gains tax and defines the small businesses that are eligible for preferential treatment.

Congress's original intent in enacting Section 1202 was to stimulate investment in small businesses. President Obama and the 111th Congress further emphasized the importance of small business investment by enacting a law temporarily allowing 100% of gains from the sale of qualified small business stock to be excluded from capital gains taxation. Thus, investors in qualified small businesses are eligible for a zero percent capital gains rate on their sale of certain qualified stock through the end of 2011. However, despite Congress's support for stimulating investment in small and start-up businesses, Section 1202, which defines the qualified small business stock eligible for an exclusion from capital gains taxation, is too limited and presents technical challenges which investors in small innovative companies are unable to overcome. Among other challenges, Section 1202 employs a test in which a corporation's gross assets must be less than $50 million immediately before and after the stock is issued in order to be eligible for preferred capital gains treatment. When intellectual property (IP) is incorporated as an asset, small biotech companies are almost always over the $50 million limit. The high value of our IP

belies the fact that our emerging companies are small businesses that need support if they are going to continue to work toward important medical breakthroughs.

As I have mentioned, venture capital funding is very limited in Montana, so incentives for further investment in our industry are much-needed. Modifications to the small business stock rules under Section 1202 so that they more accurately represent the state of innovative small businesses in America could provide a critical capital infusion for small biotechs.

Small Business Early-Stage Investment Program

Last year, the House of Representatives took action to assist early-stage venture-backed businesses like those in the biotechnology industry. In June, it passed the Small Business Early-Stage Investment Program as a part of the Small Business Lending Fund Act of 2010. This program would provide $1 billion in matching funds for venture capital investments in certain industries, including life sciences. These funds would serve as matching dollars for venture capitalists that have already raised an equivalent amount of capital from private sector sources. The government would essentially double the seed financing for venture capitalists who are investing in biotech startups.

In order to participate, an investment company like a venture fund would have to submit a business plan describing its investment strategy in early-stage small businesses in targeted industries, information about the expertise of the management team, and the likelihood of success and profitability. A participating investment company would have to make all of its investments in small business concerns, 50% of which would have to be early-stage small businesses, defined as domestic businesses with less than $15 million in gross annual sales revenues for the previous 3 years. If a venture group qualified, it would use its grant from the SBA to double its investment in an early-stage small business.

Under the program, the SBA's grants would be treated the same as investments by other limited partners in an investment fund, except that the SBA would not receive any control or voting rights with respect to the early-stage small business. Ideally, over time, the SBA's investment program would become self-sustaining as funds from successful small businesses were repaid into a revolving fund. This would allow the SBA to continue to provide matching grants for venture capitalists to extend lifelines to even more early-stage high tech companies.

This legislation has the potential to significantly increase the flow of capital into small, early-stage biotechnology companies. In turn, it would give biotech startups the opportunity to conduct their groundbreaking research to find cures and treatments for patients while providing high-paying jobs for American workers.

Angel Investor Tax Credit

Congress could look to the states for examples of how to spur biotech innovation. Over 20 states have implemented angel investor tax credit programs, in which individual taxpayers are incentivized to invest in small innovative businesses like mine. While Montana does not have an angel investor tax credit program, angel investors continue to play a significant role in early-

stage financing of our small biotechnology companies. A federal angel tax credit program would encourage additional financing from these valuable investors during a biotech's seed stage of development.

Angel investors are the main source of capital for about 50,000 companies each year in the United States, but that number could decrease significantly unless action is taken to promote investment and minimize risk. Many states have recognized the importance of angel investors and implemented tax credit programs reimbursing angels for 25% to 50% of their qualified investments in biotechnology startups and other small businesses. This investment by the states makes clear the important impact that innovation can have on the national level. It is imperative that Congress look at measures the federal government could take that would spur seed investing vital to the beginning of the research and development process.

R&D Partnership Structures

Congress's support for biotechnology is critical in this uncertain economic climate. Historically, Congress has provided tax incentives to high-risk industries as a means of encouraging investment in new endeavors which it deems important. Research and development in the biotechnology industry is an extremely high-risk undertaking with substantial start-up costs, a lengthy time period, and the possibility that the technology will not be commercially viable. Biotech companies face hurdles in finding and developing new resources and diversifying risk while also expending substantial financial resources on research and development before successful FDA approval.

Allowing investors in high-risk biotech startups to take advantage of tax benefits accumulated during the long development process would create a powerful incentive structure for private investment in this often uncertain industry. By permitting biotech companies to drop their R&D projects into joint ventures with investors to pass through their tax benefits, R&D partnership structures would provide key early funding for startup biotechs while also keeping investors engaged. As Congress looks to maintain U.S. competitiveness in the global economy and lead the effort to cure and treat diseases, it should look to tax incentives that encourage investment despite the high-risk nature of the biotechnology industry.

Closing Remarks

The U.S. biotechnology industry remains committed to developing a healthier American economy, creating high-quality jobs in every state, and improving the lives of all Americans. Additionally, the medical breakthroughs happening in labs across the country could unlock the secrets to curing the devastating diseases that affect all of our families. While I am appreciative of the steps Congress has taken to support and inspire biotechnology breakthroughs, further investment is needed if the United States is to hold its place as a leader in creating new medicines and cures. While there is no single solution to the challenges facing our industry, the portfolio of options I have presented will help startup biotech companies in Montana and across the nation weather the current economic storm and continue working toward delivering the next generation of medical breakthroughs – and, one day, cures – to patients who need them.